REMARKS

The Office Action indicates that 20 claims are pending in the application. Applicants respectfully submit that, in conformance with the Preliminary Amendment submitted June 14, 2005, Claims 1 through 19 and new Claims 20 through 24 are pending in the application.

Claim 1 has been amended to emphasize that the inventive agents advantageously provide a greater reduction in the cholesterol level than the sum of the effects when the carob fiber, n-3 fatty acid or cholesterol-reducing active compound are administered alone. Support for this amendment can be found in the Application-as-filed, for example on Page 18, lines 9 through 15.

Claim 5 has been amended to reflect advantageous embodiments in which the n-3 fatty acid is a single polyunsaturated fatty acid having a chain length > C12. Support for this amendment can be found in the Application-as-filed.

Claims 20 through 24 have been added to complete the record for examination and highlight particularly advantageous embodiments of the invention.

Claim 20 reflects advantageous embodiments in which the water-insoluble carob fiber is administered in a daily dose ranging from 1 to 15 g. Support for Claim 20 can be found in the Application-as-filed, for example on Page 16, lines 20 through 24.

Claim 21 reflects advantageous embodiments in which the n-3 fatty acid is derived from vegetable oil or oils from microorganisms. Support for Claim 21 can be found in the Application-as-filed, for example on Page 11, lines 12 through 14.

Claim 22 reflects advantageous products of the invention in which the n-3 fatty acid consists of one or more of: all-cis-9,12,15-octadecatrienoic acid (ALA), all-cis-6,9,12,15-octadecatetraenoic acid, all-cis-11,14,17-eicosatrienoic acid, all-cis-13,16,19-docosatrienoic acid,

all-cis-7,10,13,16,19-docosapentaenoic acid (DPA) and all-cis-4,7,10,13,16, 19-docosahexaenoic acid (DHA). Support for Claim 22 can be found in the Application-as-filed.

Claim 23 reflects advantageous embodiments in which synergy is provided by n-3 fatty acid administered in a daily dose ranging from 50 mg to 600 mg. Support for Claim 23 can be found in the Application-as-filed, for example on Page 16, lines 30 through 32 and lines 16 through 19 in conjunction with Page 20, line 21.

Claim 24 reflects advantageous embodiments in which the cholesterol-reducing compound is present at 10 to 50% of the dosage which would be recommended in the absence of said carob product and said n-3 fatty acid. Support for Claim 24 can be found in the Application-as-filed, for example on Page 17, lines 3 through 6.

Reexamination and reconsideration of this application, withdrawal of all rejections, and formal notification of the allowability of the pending claims are earnestly solicited in light of the remarks which follow.

Submission of Terminal Disclaimer

Claims 1 through 11 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting in light of co-pending Application No. 10/538,903. Solely to advance prosecution of the case and without addressing the merits of the rejection, Applicants respectfully submit herewith a terminal disclaimer, as suggested by the Examiner. More particularly, Applicants submit herewith a terminal disclaimer that disclaims the terminal part of any patent granted on the above-identified application extending beyond the expiration date of the full statutory term which may ultimately result from any patent granted from the cited co-pending application, i.e. Application No. 10/538,903.

Applicants thus respectfully request withdrawal of the foregoing double patenting rejection upon entry of the enclosed terminal disclaimer.

Claim Objections/Rejections under 35 USC 101 and 112

Claims 9, 10, 14, 15, 19 and 20 stand objected to as being in improper multiple dependent claims. Applicants' Representative respectfully submits that Claims 9, 10, 14, 15, 19 and 20 were amended into conventional dependent claims in conformance with United States practice in Applicants' Preliminary Amendment of June 14, 2005. The Examiner's attention is kindly directed to the PTO Patent Application Information Retrieval (PAIR) System; Image File Wrapper; Mail Room Date: 06-14-2005; Document Descriptions: Preliminary Amendment and Claims.

Claims 15 through 20 stand rejected because the claimed recitation of a use. Applicants' Representative respectfully submits that the noted "use" claims, permitted under European practice, were likewise amended into product claims, in conformance with United States practice in Applicants' Preliminary Amendment of June 14, 2005. The Examiner's attention is again kindly directed to the PTO PAIR System; Image File Wrapper; Mail Room Date: 06-14-2005; Document Descriptions: Preliminary Amendment and Claims.

Accordingly, Applicants respectfully request withdrawal of the foregoing objection/rejections.

The Office Action indicates that Claims 1 through 20 are pending. Applicants' Representative submits that the International Application initially contained 20 claims. However, the claim set was amended to 19 claims during International prosecution. Accordingly, Applicants' Preliminary Amendment included 19 claims. Based on the difference in total number of claims, Applicants' Representative submits that the Examiner may be considering the International claim set, although the PAIR System indicates that the Preliminary Amendment of June 14th was entered. If there is an administrative error of some sort, or if it

would be of any assistance, Applicants' Representative is prepared to cancel all claims and provide a new claim set beginning at Claim 25.

The Claimed Invention is Patentable
in Light of the Art of Record

Claims 1 through 20 stand rejected over United States Patent No. 5,856,313 ("US 313") to Marco et al. in combination with United States Patent No. 5,502,077 ("US 077") to Breivik et al. and McKenney (Lipid Management).

It may be useful to briefly consider the invention before addressing the merits of the rejection.

Broad sections of the population currently suffer from elevated blood cholesterol values. A number of therapeutic active compounds are prescribed for treating high cholesterol, including statins and the like. All of such therapeutic active compounds must be taken under medical supervision and monitoring. Furthermore, to achieve the therapeutic aims, sometimes considerable concentrations have to be used. Here, unwanted, sometimes life-threatening side effects can occur. Combinations of therapeutic active compounds can be used, however, such combinations can have hazardous contraindications. For instance, combinations of fibrates with statins demonstrate an increased risk of myopathy syndromes. Combinations of cerivastatin with gemfibrozil can be fatal.

A number of food components are known to positively effect cholesterol, as well. Unfortunately, the effects which can be achieved with such food components are significantly below those which are achieved using therapeutic active compounds, and are thus far lower than desirable. Furthermore, antagonistic actions have been found between combined food components. The combination of water insoluble carob fiber and viscous dietary fiber derived from carob seed meal has been shown to be detrimental to blood cholesterol levels, for example.

(The Examiner's attention is kindly directed to the Application-as-filed at Page 5, lines 4 through 16).

Altogether unexpectedly, Applicants have found that a combination of carob product, n-3 fatty acid and cholesterol-reducing active compound provides a synergistic reduction in cholesterol levels.

Accordingly, the claims are directed to cholesterol-reducing agents that include at least one carob product, at least one n-3 fatty acid and at least one cholesterol-reducing active compound. Surprisingly, the inventive agent provides a greater reduction in cholesterol levels than the sum of the effects when the carob fiber, n-3 fatty acid and cholesterol-reducing active compound are administered alone, as recited in the amended claims.

In advantageous embodiments, the synergy is imparted through use of a single n-3 fatty acid having a chain length > C12, as recited in Claim 5 as-amended.

In beneficial aspects of such advantageous embodiments, the single n-3 fatty acid is all-cis-4,7,10,13,16,19-docosahexaenoic acid (DHA), as recited in Claim 8.

The cited references do not teach or suggest the claimed invention.

US 313 is generally directed to methods of making carob fiber. US 313 discloses a nine step method of extracting water insoluble carob fiber from carob pods. (Col. 1, line 53 – Col. 3, line 44). US 313 expressly notes the particle size of flour made from its fiber. (Col. 4, lines 5 – 10). US 313 is curiously silent as to the length of the fibers it produces, however, other than a reference in its figure to "fine," "medium" and "coarse" fiber. (Figure). US 313 merely generally indicates that carob fiber of indeterminant length, ingested alone, has a hypocholesterolaemiant effect when provided as 5% of an animal's diet. (Col. 5, lines 1 - 28).

US 313 thus does not teach or suggest the claimed invention.

US 313 specifically does not teach or suggest the recited synergistic cholesterol-reducing agent that includes a combination of carob fiber product, n-3 fatty acid and at least one cholesterol-reducing active compound which provides a greater reduction in cholesterol level than the sum of the effects when the carob, n-3 fatty acid or cholesterol-reducing active compound are administered alone. Applicants respectfully make of record that, in contrast to the urgings of the Office Action, the recited components provide more than an "additive effect," as indicated numerous times in the Application-as-filed. MPEP 2144.09 (presence of synergy rebutting *prima facie* obviousness rejection).

Nor does US 313 teach or suggest the advantageous inventive agents in which synergy is imparted by a single n-3 fatty acid having a chain length > C12, as recited in Claim 5.

Thus US 313 most certainly does not teach or suggest such agents in which the n-3 fatty acid is all-cis-4,7,10,13,16,19-docosahexaenoic acid (DHA), as recited in Claim 8.

Nor does US 313 teach or suggest the administration of the advantageous inventive agent containing carob in a daily dose ranging from 1 to 15 g, as recited in Claim 20. US 313 instead discloses the administration of carob in significantly higher dosages, i.e. at 5% of an animal's daily diet. Applicants respectfully submit that the USDA's recommended 2000 calorie diet contains approximately 466 g of nutrients. Accordingly, US 313's percentage converts into a daily weight dosage of approximately 23 g of fiber per day, or 35% more fiber than recited within the advantageous embodiments of Claim 20.

US 313 likewise fails to teach or suggest the advantageous embodiments of Claims 21 through 24.

Accordingly, Applicants respectfully submit that US 313 does not teach or suggest the claimed invention, considered either alone or in combination with the remaining art of record.

US 077 does not cure the deficiencies in US 313.

US 077 is directed to a particular mixture of DHA and EPA fatty acids which are said to have a positive effect on the risk factors for cardiovascular diseases. (Col. 2, lines 50 – 56 and lines 63 - 67). US 077 expressly indicates that "[t]o our knowledge there is nothing to suggest that DHA alone has any effect on the blood pressure." (Col. 2, lines 26 – 27). US 077 similarly notes several earlier studies disclosing that EPA alone does not have a significant effect on hypertension. (Col. 2, lines 1 – 16). The DHA/EPA fatty acid blend is formed by subjecting marine oil to numerous processes, including esterification, urea fractionation and molecular distillation. (Col. 3, lines 24 – 29). US 077 indicates that the fractionation removes esters having a chain length below C20. (Col. 3, lines 30 – 32). Distillation is then used to "upgrade" either the DHA or EPA fraction (as appropriate) into the required 1:1 to 2:1 ratio. (Col. 3, lines 60 – 65). US 077's working examples indicate that about 5 g of its fatty acid mixture is administered daily. (Col. 6, lines 49 – 58).

US 077 likewise fails to teach or suggest the recited synergistic cholesterol-reducing agents that include a combination of carob product, n-3 fatty acid and cholesterol-reducing active compound which provide a greater reduction in cholesterol level than the sum of the effects when the carob, n-3 fatty acid or cholesterol-reducing active compound are administered alone. In fact, US 077 teaches away from the beneficial synergies between carob and fatty acid by instead touting a combination of fatty acids as providing advantageous results.

Nor does US 077 teach or suggest the advantageous agents of Claim 5, in which the synergistic effect is imparted by a single n-3 fatty acid having a chain length > C12, for numerous reasons. US 077 clearly indicates that all fatty acids having chain lengths of less than 20 are removed from its marine oil. Furthermore, to modify US 077 so as to avoid the required

inclusion of two fatty acids would clearly render US 077 unfit for its intended purpose. MPEP 2143.01 (citing *In re Gordon*, 221 USPQ 1125 (Fed. Cir. 1984)).

Thus US 077 most certainly does not teach or suggest such agents in which the single n-3 fatty acid is all-cis-4,7,10,13,16,19-docosahexaenoic acid (DHA), as recited in Claim 8.

US 077 likewise can not teach or suggest the advantageous inventive agents in which the n-3 fatty acid consists of one or more of: all-cis-9,12,15-octadecatrienoic acid (ALA), all-cis-6,9,12,15-octadecatetraenoic acid, all-cis-11,14,17-eicosatrienoic acid, all-cis-13,16,19-docosatrienoic acid, all-cis-7,10,13,16,19-docosapentaenoic acid (DPA) and all-cis-4,7,10,13,16,19-docosahexaenoic acid (DHA), as recited in Claim 22.

Nor does US 077, directed to method of processing marine oil, teach or suggest the advantageous inventive agents in which the n-3 fatty acid is derived from vegetable oil or oils from microorganisms, as recited in Claim 21.

US 077 further does not teach or suggest the advantageous administration of an agent containing carob in a daily dose ranging from 1 to 15 g, as recited in Claim 20.

And US 077 most certainly does not teach or suggest the synergy provided by the advantageous administration of an agent containing n-3 fatty acid in a daily dose ranging from 50 mg to 600 mg, as recited in Claim 23. US 077 instead teaches away from such embodiments by disclosing the daily administration of approximately 5 g within its working examples.

Accordingly, Applicants respectfully submit that US 077 does not teach or suggest the claimed invention, considered either alone or in combination with the remaining art of record.

Lipid Management does not cure the deficiencies in either of the foregoing references.

Lipid Management merely presents an overview of various cholesterol-reducing drugs, including statins, bile acid resins and the like. Lipid Management expressly notes that statins prescribed at higher doses may induce side effects. (S302) Lipid Management goes on to disclose that a combination of cholesterol-reducing drugs may be used. (S303). Lipid Management generically notes in its introduction that "dietary adjuncts" such as fiber may be used or that fish containing omega-3 fatty acids may be consumed.

Accordingly, Lipid Management likewise fails to teach or suggest the recited synergistic cholesterol-reducing agents that include a combination of carob product, n-3 fatty acid and cholesterol-reducing active compound which provide a greater reduction in cholesterol level than the sum of the effects when the carob, n-3 fatty acid or cholesterol-reducing active compound are administered alone. In fact, Lipid Management teaches away from the beneficial synergies imparted by carob and fatty acid by instead expressly touting drug combinations as providing advantageous results.

And Lipid Management, generically referencing the consumption of fish, most certainly does not teach or suggest such agents in which the single n-3 fatty acid is all-cis-4,7,10,13,16,19-docosahexaenoic acid (DHA), as recited in Claim 8.

Lipid Management likewise can not teach or suggest the advantageous inventive agents in which the n-3 fatty acid consists of one or more of: all-cis-9,12,15-octadecatrienoic acid (ALA), all-cis-6,9,12,15-octadecatetraenoic acid, all-cis-11,14,17-eicosatrienoic acid, all-cis-13,16,19-docosatrienoic acid, all-cis-7,10,13,16,19-docosapentaenoic acid (DPA) and all-cis-4,7,10,13,16,19-docosahexaenoic acid (DHA), as recited in Claim 22.

Nor does Lipid Management, broadly recommending fish consumption, teach or suggest the advantageous inventive agents in which the n-3 fatty acid is derived from vegetable oil or oils from microorganisms, as recited in Claim 21.

Lipid Management further does not teach or suggest the advantageous administration of an agent containing carob in a daily dose ranging from 1 to 15 g, as recited in Claim 20.

Lipid Management likewise fails to teach or suggest the synergy provided by the advantageous administration of an agent containing n-3 fatty acid in a daily dose ranging from 50 mg to 600 mg, as recited in Claim 23.

And Lipid Management most certainly does not teach or suggest advantageous inventive agents in which the cholesterol-reducing active compound is present at 10 to 50% of the dosage which would be recommended in the absence of carob product and n-3 fatty acid. As noted above, Lipid Management instead teaches away from the synergistic inventive combination of particular food components and cholesterol-reducing active compound by touting the benefits of drug combinations alone.

Accordingly, Applicants respectfully submit that Lipid Management does not teach or suggest the claimed invention, considered either alone or in combination with the remaining art of record.

There would have been no motivation to have combined US 313, US 077 and Lipid Management. Applicants respectfully submit that merely because the references can be combined is not enough, there must still be a suggestion. MPEP 2143.01 (section citing Mills). US 313 is directed to methods of making carob flour. US 077 is directed to methods by which to produce a particular fatty acid blend from marine oil. Lipid Management is merely an overview of various cholesterol-reducing drugs. These are altogether different fields of endeavor and problems solved, to say the least.

Applicants respectfully submit that the Office Action is instead indulging in impermissible hindsight by merely picking and choosing elements from the prior art while using the instant specification as the guide for that selection process. In particular, an antagonistic

action was found for food component mixtures including the recited carob, as noted above. Consequently, there would have been no motivation to have combined the carob product with another food component as there would have been no expectation of success.

However, even if combined (which Applicants submit should not be done), the claimed invention would not result.

The combination specifically fails to teach or suggest that the recited synergistic cholesterol-reducing agents including a combination of carob product, n-3 fatty acid and cholesterol-reducing active compound would provide a greater reduction in cholesterol level than the sum of the effects when the carob, n-3 fatty acid or cholesterol-reducing active compound are administered alone. As noted above, carob was known at the time of the invention to potentially provide an antagonistic effect when used in combinations. Thus, in contrast to the urgings of the Office Action, there would have been no reasonable expectation of success upon the combination of carob product and an additional food component.

Furthermore, the secondary references clearly teach away from the unexpected synergy between carob, fatty acid and cholesterol-reducing active compound. US 077 clearly indicates that synergy is provided by its combination of particular fatty acids in specific ratios. Lipid Management indicates that synergy is provided by a combination of drugs.

And combination most certainly does not teach or suggest the advantageous agents of Claim 5, in which a synergistic effect is imparted by a single n-3 fatty acid having a chain length > C12. US 077, cited by the Office Action for its use of fatty acids, clearly indicates that all fatty acids having chain lengths of less than 20 are removed from its marine oil. Furthermore, to modify the secondary reference so as to avoid the required inclusion of two fatty acids would clearly render it unfit for its intended purpose, as noted above.

Thus the combination most certainly does not teach or suggest such agents in which the single n-3 fatty acid is all-cis-4,7,10,13,16,19-docosahexaenoic acid (DHA), as recited in Claim 8.

The combination likewise can not teach or suggest the advantageous inventive agents in which the n-3 fatty acid consists of one or more of: all-cis-9,12,15-octadecatrienoic acid (ALA), all-cis-6,9,12,15-octadecatetraenoic acid, all-cis-11,14,17-eicosatrienoic acid, all-cis-13,16,19-docosatrienoic acid, all-cis-7,10,13,16,19-docosapentaenoic acid (DPA) and all-cis-4,7,10,13,16,19-docosahexaenoic acid (DHA), as recited in Claim 22.

Nor does the combination, whose secondary reference (US 077) is directed to methods of processing marine oil, teach or suggest the advantageous inventive agents in which the n-3 fatty acid is derived from vegetable oil or oils from microorganisms, as recited in Claim 21.

The combination, disclosing a dosage of 5 % of daily diet for carob within US 313 and 5 g daily of a combination of particular acids in specific ratios in US 077, likewise fails to teach or suggest the beneficial synergistic amounts of the invention, such as the carob amounts of Claims 20 and n-3 fatty acid amounts of Claim 23.

And the combination most certainly does not teach or suggest the advantageous inventive agents in which the cholesterol-reducing compound is present at 10 to 50% of the dosage which would be recommended in the absence of the carob product and n-3 fatty acid.

Accordingly, Applicants respectfully submit that Claims 1 through 24 are patentable in light of US 313, US 077 and Lipid Management considered either alone or in combination.

CONCLUSION

It is respectfully submitted that Applicants have made a significant and important contribution to the art, which is neither disclosed nor suggested in the art. It is believed that all of pending Claims 1 through 24 are now in condition for immediate allowance. It is requested that the Examiner telephone the undersigned if any questions remain to expedite examination of this application.

As requested, copies of references noted in the Information Disclosure Statement of June 6, 2005 and June 14, 2005 will be forwarded under separate cover.

It is not believed that extensions of time or fees are required, beyond those which may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time and/or fees are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required is hereby authorized to be charged to Deposit Account No. 50-2193.

Respectfully submitted,

Cathy Moore

Cathy R. Moore
Reg. No. 45,764

ProPat, L.L.C.
425-C South Sharon Amity Road
Charlotte, NC 28211-2841
Telephone: (704) 365-4881
Fax: (704) 365-4851
Customer No. 38263

Application No.: 10/539,174
Filing Date: June 14, 2005
Page: 19

CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that this correspondence is being facsimile transmitted to the United States Patent and Trademark Office at facsimile number (571) 273-8300 on October 6, 2006.

Cathy Moore